

§ 830.10

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may vary from one shipment to another.

Small business means a medical device manufacturer with 500 or fewer employees, or a medical device relabeler or repackager with 100 or fewer employees.

Specification means any requirement with which a device must conform.

Unique device identifier (UDI) means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of § 830.20. A UDI is composed of:

(1) A *device identifier*—a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device; and

(2) A *production identifier*—a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:

(i) The lot or batch within which a device was manufactured;

(ii) The serial number of a specific device;

(iii) The expiration date of a specific device;

(iv) The date a specific device was manufactured.

(v) For an HCT/P regulated as a device, the distinct identification code required by § 1271.290(c) of this chapter.

Universal product code (UPC) means the product identifier used to identify an item sold at retail in the United States.

Version or model means all devices that have specifications, performance, size, and composition, within limits set by the labeler.

Subpart B—Requirements for a Unique Device Identifier

§ 830.10 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Food and Drug Administration must publish notice of change in the FEDERAL REGISTER and the material must be available to the public. All approved material is available for inspection at the Division of Dockets

Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 301-827-6860, and is available from the source listed in paragraph (b) of this section. Copies are also available for purchase from the American National Standards Institute (ANSI), mailing address: ANSI, Attn: Customer Service Department, 25 West 43rd St., 4th floor, New York, NY 10036, phone: 212-642-4980, and may be ordered online at <http://webstore.ansi.org/>. The material is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(b) International Organization for Standardization (ISO), mailing address: ISO, Attn: ISO Central Secretariat, 1, ch. de la Voie-Creuse, Case postale 56, CH-1211 Geneva 20, Switzerland, phone (dialing from the United States): 011-41-22-749-0111, and may be ordered online at <http://www.standardsinfo.net>.

(1) ISO/IEC 646:1991(E), Information technology—ISO 7-bit coded character set for information interchange (third edition; December 15, 1991), into §§ 830.20(c) and 830.100(b);

(2) ISO/IEC 15459-2:2006(E), Information technology—Unique identifiers—Part 2: Registration procedures (second edition; March 1, 2006), into §§ 830.20(b) and 830.100(b);

(3) ISO/IEC 15459-4:2008(E), Information technology—Unique identifiers—Part 4: Individual items (second edition; July 15, 2008), into §§ 830.20(b) and 830.100(b);

(4) ISO/IEC 15459-6:2007(E), Information technology—Unique identifiers—Part 6: Unique identifier for product groupings (first edition; June 15, 2007), into §§ 830.20(b) and 830.100(b).

§ 830.20 Requirements for a unique device identifier.

A unique device identifier (UDI) must:

(a) Be issued under a system operated by FDA or an FDA-accredited issuing agency;

(b) Conform to each of the following international standards:

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(1) ISO/IEC 15459-2, which is incorporated by reference at § 830.10;

(2) ISO/IEC 15459-4, which is incorporated by reference at § 830.10; and

(3) ISO/IEC 15459-6, which is incorporated by reference at § 830.10.

(c) Use only characters and numbers from the invariant character set of ISO/IEC 646, which is incorporated by reference at § 830.10.

[78 FR 55825, Sept. 24, 2013]

§ 830.40 Use and discontinuation of a device identifier.

(a) Only one device identifier from any particular system for the issuance of unique device identifiers (UDIs) may be used to identify a particular version or model of a device. A particular version or model may be identified by UDIs from two or more systems for the issuance of UDIs.

(b) A device identifier shall be used to identify only one version or model.

(c) In the event that a version or model of a device is discontinued, its device identifier may not be reassigned to another device. If a discontinued version or model is re-introduced and no changes have been made that would require the use of a new device identifier, the device identifier that was previously in use may be used to identify the device.

(d) In the event that an issuing agency relinquishes or does not renew its accreditation, you may continue to use a previously issued UDI until such time as § 830.50 requires you to assign a new device identifier.

[78 FR 55825, Sept. 24, 2013]

§ 830.50 Changes that require use of a new device identifier.

(a) Whenever you make a change to a device that is required to bear a unique device identifier (UDI) on its label, and the change results in a new version or model, you must assign a new device identifier to the new version or model.

(b) Whenever you create a new device package, you must assign a new device identifier to the new device package.

[78 FR 55825, Sept. 24, 2013]

§ 830.60 Relabeling of a device that is required to bear a unique device identifier.

If you relabel a device that is required to bear a unique device identifier (UDI), you must:

(a) Assign a new device identifier to the device, and

(b) Keep a record showing the relationship of the prior device identifier to your new device identifier.

[78 FR 55825, Sept. 24, 2013]

Subpart C—FDA Accreditation of an Issuing Agency

§ 830.100 FDA accreditation of an issuing agency.

(a) *Eligibility.* A private organization may apply for accreditation as an issuing agency.

(b) *Accreditation criteria.* FDA may accredit an organization as an issuing agency, if the system it will operate:

(1) Will employ unique device identifiers (UDIs) that meet the requirements of this part to adequately identify a device through its distribution and use;

(2) Conforms to each of the following international standards:

(i) ISO/IEC 15459-2, which is incorporated by reference at § 830.10;

(ii) ISO/IEC 15459-4, which is incorporated by reference at § 830.10;

(iii) ISO/IEC 15459-6, which is incorporated by reference at § 830.10.

(3) Uses only characters and numbers from the invariant character set of ISO/IEC 646, which is incorporated by reference at § 830.10.

(4) Will be available to all users according to a single set of consistent, fair, and reasonable terms and conditions.

(5) Will protect against conflicts of interest between the issuing agency (and its officers, employees, and other agents) and labelers (and their officers, employees, and other agents) seeking to use UDIs that may impede the applicant's ability to independently operate a fair and neutral identifier system.

§ 830.110 Application for accreditation as an issuing agency.

(a) *Application for initial accreditation.*

(1) An applicant seeking initial FDA